IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL 2327** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**
This document applies to: **WAVE 4 CASES LISTED IN EXHIBIT A TO DEFENDANTS' MOTION**	

REPLY MEMORANDUM IN SUPPORT OF MOTION TO EXCLUDE GENERAL-CAUSATION OPINION TESTIMONY OF KONSTANTIN WALMSLEY, M.D.

Plaintiffs fail to give any valid reasons why this Court should depart from its Wave 1 ruling—*In re: Ethicon Inc. Pelvic Repair Systems Product Liability Litigation*, MDL No. 2327, 2016 WL 4961675, at *3 (S.D.W. Va. Aug. 25, 2016)—that specifically excluded Dr. Walmsley's IFU opinions because he does not possess the "additional expertise" necessary to opine about what should be included in an IFU. In fact, they fail to address—or even acknowledge—this ruling at all. Instead, they restate the very same qualifications that this Court has already addressed and found insufficient for rendering the warnings opinions he offers as General Opinion No. 1 for each case identified in Exhibit A attached to Ethicon's motion (Dkt. 3585-1).

Plaintiffs likewise fail to address or acknowledge this Court's Wave 2 ruling excluding the alternative-procedures *general-causation* opinion of Nathan Goodyear, M.D.—*In re: Ethicon, Inc. Pelvic Repair Systems Product Liability Litigation*, MDL No. 2327, 2017 WL 1264620, at *3 (S.D.W. Va. Mar. 29, 2017). There should be no different result here as to the

alternative-procedures opinion Dr. Walmsley offers in Wave 4 as to General Opinion No. 2 in each plaintiff's case.

ARGUMENTS AND AUTHORITIES

I. Dr. Walmsley's IFU opinions should be excluded for the same reason they were in Wave 1 (and now Wave 2): he is not qualified to opine about what should be included in an IFU.

Dr. Walmsley's IFU opinions set forth in General Opinion Nos. 1 and 2 in these Wave 4 cases are essentially identical to those opinions offered by him in Wave 1 that this Court excluded because he "does not possess the additional expertise to offer expert testimony about what an IFU should or should not include." *In re: Ethicon Inc.*, 2016 WL 4961675, at *3. As the Court noted in its order, Dr. Walmsley's opinions focus on "whether the relevant IFU should have included warnings about particular complications." *Id.*; *see also* Defs.' Mem. (Dkt. 3586) at 3-4. Plaintiffs fail to mention the Court's Wave 1 Order in their opposition, let alone address why the same result should not occur here. Instead, Plaintiffs cite case law from this Court and elsewhere that precedes the Wave 1 Order, and does not involve Dr. Walmsley and the opinions that he offers both here and in Wave 1. *See* Pls.' Opp'n (Dkt. 3783) at 4-5.

Nor do Plaintiffs make any attempt to establish that Dr. Walmsley's factual circumstances have changed. They do not contend that Dr. Walmsley has since obtained the additional expertise necessary to offer his IFU opinions in the two months since this Court issued its Wave 1 Order. Because Dr. Walmsley does not possess the required expertise to opine about what should be included in an IFU, his opinions set forth in General Opinion Nos. 1 and 2 should be excluded just as they were in Wave 1, and now in Wave 2 as well. *See In re: Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2327, 2017 WL 1175399, at *1 (S.D.W. Va. Mar. 29, 2017) (adopting Wave 1 order as to Dr. Walmsley for Wave 2).

II. As this Court recognized, an alternative surgical *procedure* is not an alternative product *design*—a ruling that is not limited by state law.

Plaintiffs discount this Court's recent ruling in *Mullins v. Johnson & Johnson*, No. 2:12-cv-02952, 2017 WL 711766 (S.D.W. Va. Feb. 23, 2017)—"an alternative, feasible design must be examined in the context of products—not surgeries or procedures" (*id*. at *2)—claiming it is limited to West Virginia law (Pls.' Opp'n (Dkt. 3783) at 4).

Mullins is not so limiting. Even though decided under West Virginia law, this Court relied on the Fourth Circuit's decision in *Talley v. Danek Medical, Inc.*, 179 F.3d 154 (4th Cir. 1999), which rejected evidence of surgical alternatives to a spinal fixation device. It first explained:

> Evidence that a surgical procedure should have been used in place of a device is not an alternative, feasible design in relation to the TVT. Whether an alternative procedure could have been performed without the use of the TVT does nothing to inform the jury on the issue of an alternative, feasible *design* for the TVT.

Mullins, 2017 WL 711766, at *2 (emphasis in original). The *Mullins* court then contrasted the difference between the choice of alternative surgical procedures with the task of opining about an alleged design-defect claim:

> Instead, alternative surgeries or procedures raise issues wholly within the context of what a treating physician has recommended for patients based on the individual needs and risk factors associated with individual patients. In other words, alternative surgeries or procedures concern the medical judgment of the doctors who use TVT devices to treat stress urinary incontinence ("SUI"); other surgeries or procedures do not inform the jury on *how* the TVT's design could have feasibly been made safer to eliminate the risks that caused the plaintiffs' injuries.

Id.

Even more recently, this Court applied this rule of law broadly in the Main MDL when it resolved a general-causation challenge to the alternative-procedures opinion of Nathan Goodyear, M.D. There, the Court recognized that a medical device *product* is not defective in

design simply because alternative surgical and nonsurgical *procedures* may exist—and this holding was not dependent upon the law of any particular jurisdiction. *See In re: Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2327, 2017 WL 1264620, at *3 (S.D.W. Va. Mar. 29, 2017) (excluding the general-causation, alternative-procedures opinion testimony of Dr. Goodyear after "agree[ing] with Ethicon that alternative procedures/surgeries do not inform the issue of whether an alternative design for a product exists").[1]

As in these cases, alternative surgical *procedures* say nothing about the availability of a technically feasible alternative *product design* or formulation. Given that the premise behind *Mullins*, *Talley* and now *In re: Ethicon* applies with equal force here, Dr. Walmsley's alternative-procedures opinion should likewise be excluded in its entirety because an alternative method of surgical treatment is not an alternative design that can support a claim for design defect.

Plaintiffs' attempts to otherwise establish relevance fall flat. Plaintiffs' risk-benefit argument (Pls.' Opp'n (Dkt. 3783) at 6) should be rejected because a risk-benefit analysis is part of the analysis for design defect, which rests on the existence of an alternative design, and an alternative surgical *procedure* is not an alternative *design* that would support a claim for design defect. *See* Defs.' Mem. (Dkt. 3586) at 4-5. Further, Plaintiffs cite no legal authority to support

[1] *Mullins*, *Talley*, and *In re: Ethicon* are not outliers. Numerous courts around the country have similarly found surgical alternatives irrelevant to design defect claims. *See, e.g.*, *Theriot v. Danek Med., Inc.*, 168 F.3d 253, 255-56 (5th Cir. 1999); *Schmidt v. C.R. Bard, Inc.*, No. 2:11-cv-00978, 2013 WL 3802804, at *2 (D. Nev. July 22, 2013); *Linsley v. C.R. Bard, Inc.*, No. 98-2007, 2000 WL 343358, at *3 (E.D. La. Mar. 30, 2000); *Bogle v. Sofamor Danek Grp., Inc.*, No. 95-8646, 1999 WL 1132313, at *4 (S.D. Fla. Apr. 9, 1999); *Sita v. Danek Med., Inc.*, 43 F. Supp. 2d 245, 256 (E.D.N.Y. 1999); *Hosford v. BRK Brands, Inc.*, Nos. 1140899 & 1140901, 2016 WL 4417256, at *8 (Ala. Aug. 19, 2016). Simply put, "alternative methods of treatment are *not* alternative designs." *Hornbeck v. Danek Med., Inc.*, No. 99-30966, 2000 WL 1028981, at *1 (5th Cir. July 5, 2000) (emphasis in original).

their argument that Dr. Walmsley's alternative-procedures opinions are relevant to show "Ethicon's reasonableness in putting these devices on market" or to support a claim for punitive damages. Pls.' Opp'n (Dkt. 3783) at 6-7.

In fact, Plaintiffs' opposition makes clear they intend to offer Dr. Walmsley's alternative-procedures opinions for at least two improper purposes. First, this opinion ultimately challenges the decision of Plaintiffs' surgeons to implant Ethicon's mesh devices rather than use one of the alternative surgical procedures identified by Dr. Walmsley. *See* Defs.' Mem. (Dkt. 3586) at 4. Thus, Plaintiffs are asking this Court allow the jury to find Ethicon liable essentially because Dr. Walmsley would have selected a different surgical procedure for Plaintiffs. They cite no authority permitting a physician's choice in surgical procedure to lead to manufacturer liability for a defective product, and therefore, the use of Dr. Walmsley's alternative-procedures opinion for this purpose should not be permitted.

Second, Plaintiffs would use Dr. Walmsley's alternative-procedures opinion to lead the jury to find it "less reasonable" that Ethicon ever marketed the TVT products at all. *See* Pls.' Opp'n (Dkt. 3783) at 6-7 (making repeated references to the issue of the reasonableness of Ethicon's decision to market, and to continue marketing, the TVT products). But again, Plaintiffs point to no legal authority that permits manufacturer liability for merely marketing a product. There is none. *See, e.g.*, *Jones v. Amazing Prods., Inc.*, 231 F. Supp. 2d 1228, 1250 n.25 (N.D. Ga. 2002) (declining to recognize a claim that the product should not have been marketed, noting that "perhaps the best place for a determination whether a product should be banned is a legislative or regulatory body, not a court").

Plaintiffs have shown that they intend to use Dr. Walmsley's alternative-procedures opinion for improper purposes. They should not be permitted to do so.

CONCLUSION

Ethicon asks this Court to grant its Motion to Exclude the General-Causation Testimony of Konstantin Walmsley, M.D., and limit his opinions for the reasons stated above and in its memorandum in support of its Motion.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on May 4, 2017, I electronically filed this document with the clerk of the court using the CM/ECF system, which will send notification of this filing to CM/ECF participants registered to receive service in this MDL.

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